REMARKS

In the present application, claims 1-20 have been cancelled and new claims 21-31 are pending with new claim 21 as the only independent claim. Claims 22-31 are dependent claims which depend either directly or indirectly from independent claim 21.

The Present Application Is Specifically Directed To A Cardiac Ablation Apparatus

Because the Examiner is relying on patents that concern coagulation, desiccation, incision or vessel sealing, which are very different objectives that employ substantially different methods and apparatus from the present invention, the following discussion of claim 21 and the particular benefits of the present invention to cardiac ablation is provided.

First, it must be emphasized that new claims 21-31 of the present application are generally directed to an apparatus for forming a narrow ablation line in cardiac tissue. More specifically, independent claim 21 is expressly directed to a device for clamping and ablating cardiac tissue. As recited in claim 21, such device includes first and second jaws which are relatively movable between open and clamped positions. Each jaw has opposed clamped surfaces, which each have a width. In accordance with claim 21, first and second elongated conductive ablation members are carried by the respective jaws and are adapted to be connected to a bipolar RF energy source. Each conductive ablation member has a surface contoured to engage tissue clamped between the jaws without cutting. Further, the ablation members are positioned to provide an ablation line through tissue which is substantially narrower than the width of the clamping surface. As further recited in claim 21, each jaw comprises at least three distinct elements that include: (1) an elongated support member supporting substantially the entire

length of its associated conductive ablation member; (2) the first or second elongated conductive ablation member; and (3) an insulator disposed between the conductive member and the support member.

It should be noted that the ablation called for in the present claims is a medical procedure which treats abnormal heart rhythms, e.g., atrial fibrillation. The claimed apparatus beneficially provides for the formation of controlled ablation line(s) in tissue to create scar tissue that blocks the pathway of an abnormal electrical impulse but otherwise does not substantially impair the function of the heart tissue. Thus, the narrow ablation line created by the claimed apparatus blocks the abnormal electrical impulse from being conducted through the heart, allowing the normal conduction of impulses through the proper pathway to control heart rhythm, without cutting, desiccating or coagulating the tissue in the manner described in the cited art.

In the present invention, the ablation line is created using a bipolar radiofrequency (RF) energy that is applied to conductive members carried by the jaws of the ablation apparatus. Among the benefits provided by the ablation apparatus of the present application, energy is applied to the tissue between the closed jaws only to the extent to disrupt or break the pathway of the aberrant electrical impulse by forming a relatively narrow line of ablation that avoids other damage to cardiac tissue such as damage that may result from thermal spread or sealing of tissue walls together.

Applicant's disclosure describes and shows that the illustrated apparatus provides a much narrower ablation line as compared to the clamping area provided by the jaws. In Figs. 28-32, the conductive/jaw member arrangement shows that the

tissue contacting portion of each conductive electrode is substantially narrower than the associated clamping surface. At paragraph 100 of the published application, applicant's specification discloses that:

> Importantly, Fig. 9 shows that the electrode/clamped configuration provides a clamped zone of tissue that is wider than the tissue zone of ablated tissue. This is achieved by using an electrode that is narrower than the clamped tissue width, and preferably less than one-third of the clamped tissue width.

At paragraph 101 of the published application, applicant's disclosure states, among other things: "the distance between the electrodes is minimized, so that the ablation zone remains narrow." (emphasis added). Thus, when the conductive ablation members are connected to an electrical energy source, such electrical energy is conducted between the conductive ablation members along a corresponding narrow line or zone of ablation.

Applicant's disclosure explains several added benefits of the claimed conductive member/jaw arrangement. Among such benefits, in paragraph 101, applicant's disclosure expressly teaches a reduced risk associated with thrombus formation by providing a narrower ablation zone than the clamping zone.

In addition, the claimed conductive ablation member/jaw arrangement in claim 21 beneficially provides surfaces that are contoured to engage tissue clamped between the jaws without cutting. This feature is shown and described in the current application, among other benefits, at paragraph 103:

> [0103] This "clamping" method and device for creating transmural lesions has a number of advantages. First, using a two step method as shown allows for clamping and ablation of atrial tissue without stopping the blood flow from the pulmonary vein. Secondly, by clamping both walls together, and delivering energy through the clamped tissue, the atrial tissue is not

> penetrated. Because the atrial tissue is not penetrated, a larger jaw can be used, and the clamping force can be much higher because of the increased stiffness of the jaw. Also, there is no concern of bleeding from an atrial puncture. (Emphasis added).

Several examples of this claimed feature are also shown in Figures 28-40 of the current application.

As also disclosed in Figures 28-40 in the present application, claim 21 requires that each jaw has three separate and distinct elements which include the associate conductive ablation member, an elongated support member supporting substantially the entire length of its associated conductive ablation member, and an insulator disposed between the conductive ablation member and the support member. This arrangement essentially provides a three-layered jaw construction.

Accordingly, new claims 21-31 provide an ablation apparatus having benefits as discussed above for forming relatively narrow, non-conductive lines of ablation in tissue without excessive tissue damage.

The Cited References are Significantly Different From the Claimed Ablation Apparatus

There are fundamental differences in structure and function which make clear that the Schmaltz 6,050,996, Nezhat 6,162,220 and Yamauchi 6,273,887 patents are not analogous to the claimed ablation apparatus.

It must be emphasized that each of the medical instruments disclosed in Schmaltz, Nezhat and Yamauchi are specifically designed for different and dramatically more traumatic uses than ablation. Specifically, the instrument in Schmaltz is used for "vessel sealing" which is described as "the process of liquefying the collagen in the tissue so that it crosslinks and reforms into a fused mass" which is "sufficient to permanently

close" the vessel (col. 1, lines 39-44). In Nezhat, the instrument is employed for coagulating, cutting and necrosing. As described in Schmaltz, "coagulation" is "a process of desiccating [i.e., dehydrating] tissue wherein the tissue cells are ruptured and dried." "Necrosing" causes the pathological death of tissue such as by coagulation. (Stedman's Medical Dictionary 25th Ed.) In Yamauchi, the instrument is disclosed for coagulating tissue sufficiently that such tissue may be separated by incising the tissue without undue bleeding. Consequently, each of the instruments in Schmaltz, Nezhat and Yamauchi have structural requirements and power conditions which are sufficient to dry, coagulate, cut, kill and/or seal tissue to the point at which the tissue may be severed without blood flow or the opposed walls of tissue are bonded together.

It is respectfully submitted that persons of ordinary skill would realize that such instruments are fundamentally different and clearly contrary to the requirements and conditions which are necessary for ablation. In fact, each of Schmaltz, Nezhat and Yamauchi teach substantially more traumatic medical procedures to human tissue than ablation which, if substituted for ablation, would very likely result in irreparable and potentially fatal damage to heart tissue.

In contrast, the claimed cardiac ablation apparatus only performs relative narrow levels of ablation to the extent necessary to stop the conduction of the aberrant electrical impulse. The claimed apparatus does not otherwise coagulate, desiccate, cut, kill or seal tissue in addition to performing such ablation. The claimed cardiac ablation apparatus specifically aims to minimize trauma to cardiac tissue and employs an associated structure and energy source that are commensurate with such objectives, as contrasted to the much more traumatic coagulating, desiccating, cutting and sealing

procedures of the prior art. Further, unlike the cited art, the claimed apparatus is suitable for performing such ablation without sealing the opposed tissue walls together.

Also in contrast to the claimed apparatus, the instruments disclosed in Schmaltz, Nezhat and Yamauchi do not contemplate treatment of cardiac tissue. The claimed apparatus on the other hand, is expressly directed to cardiac ablation apparatus, where it is desirable to avoid unnecessary trauma to heart tissue and minimize harm to normal heart functioning. The coagulating, cutting and sealing in the cited references do not treat heart tissue and, in fact, these references are completely silent that they may be used for cardiac tissue treatment in any way. And for good reason -- the structure and operation of those devices is inconsistent with the objectives of the present invention. Thus, not only are the disclosed coagulation, cutting and sealing instruments of Schmaltz, Nezhat and Yamauchi simply not contemplated for any use in cardiac ablation, any use of such instruments for cardiac ablation would create significant damage and destruction of heart tissue, which is counterintuitive to the benefits of ablation which aim to avoid undue trauma to heart tissue.

Further, just as Schmaltz expressly acknowledges at lines 36-37 in column 1 that there are fundamental differences between sealing and coagulation, there are also fundamental differences between such procedures and the claimed ablation apparatus for all of the above reasons.

Thus, these differences are respectfully believed to be persuasive to show that the cited references are fundamentally different and thus are not relevant to the claimed cardiac ablation apparatus.

There Is No Motivation to Make the Alleged Prior Art Combination In The Absence Of Applicant's Disclosure

It is respectfully submitted that the cited references are not combinable to render the present invention obvious, and should not be combined in view of their respective teachings. The relevant legal authority makes clear that hindsight-basis obviousness, i.e., obviousness which uses the teachings provided by the applicant's disclosure as a guide for combining references, cannot be used to render the claims obvious. As applied to the present situation, it is respectfully believed that Schmaltz, Nezhat and/or Yamauchi are not combinable in the absence of the disclosure provided by the present application.

First, Schmaltz should not be combined with the Nezhat and Yamauchi patents because they each teach or suggest opposed constructions.

As shown in Figure 1, Schmaltz teaches a bipolar electrosurgical vessel sealing instrument having removable and disposable electrodes 11 and 12. In contrast, Figure 2E of Nezhat teaches and shows bipolar forceps having electrodes that are embedded in a respective jaw and thus are not disposable or replaceable. Schmaltz specifically points out the disadvantages of prior art bipolar instrument designs that do not provide for removable or replaceable electrodes. (Col. 2, lines 54-58). The removal of the electrodes is clearly taught to be an important feature in Schmaltz such that persons of ordinary skill in the art would not be motivated to combine the removable electrode device in Schmaltz with a non-removable electrode device in Nezhat. For this reason alone, it would be contrary to the teaching of the patents to combine Schmaltz and Nezhat.

In addition, Schmaltz and Nezhat are further not combinable on the basis that Schmaltz expressly teaches that there are fundamental differences between vessel sealing which is taught

in Schmaltz, and coagulation which is the focus in Nezhat. (Col. 1, lines 36-37). Giving credence to these express differences, it would actually be contrary to their teaching and would not be obvious for either Schmaltz or Nezhat to combine one with the other.

As between Schmaltz and Yamauchi, it is respectfully submitted that these patents also are not properly combinable based on their respective teachings. The vessel sealing instrument of Schmaltz is specifically suited for sealing, bonding or fusing the opposed tissue walls together. Yamauchi is directed to an apparatus for tissue-cutting or incising as shown, for example, in the instrument in Figures 67, 74A and 74B of Yamauchi. Clearly, Schmaltz and Yamauchi teach fundamentally different constructions which would not be combinable by persons of ordinary skill in the relevant field.

Further, Nezhat should not be combined with Schmaltz or Yamauchi because the references discourage any such combination. At column 6, lines 6-11, Nezhat specifically teaches away from devices having directly opposed bipolar electrodes. This is contrary to the structures shown in Figure 1 of Schmaltz and in Figures 67, 74A and 74B of Yamauchi that have opposed bipolar electrodes.

There are also other differences which discourage any combination with Nezhat and Yamauchi. Nezhat in Figure 13 teaches a tissue-cutting structure (i.e., a knife 252) as a separate structure from the electrodes that are used to perform coagulation. Clearly, Nezhat teaches away from a structure such as in Figures 67, 74A and 74B of Yamauchi, which performs both coagulation and cutting of tissue by the same structure - - i.e., the opposed incision projections at 510a, 510b in Figure 67, and at 549a, 549b in Figures 74A and 74B.

For these reasons, Schmaltz, Nezhat and/or Yamauchi teach or suggest fundamentally different structures that are not reasonably combinable and the combination of which would not be obvious except for the improper use of the teachings provided by the Applicant's disclosure as a roadmap for making the combination.

The Claimed Combination Would Not Be Obvious Based On The Combination Of Schmaltz And Nezhat

If, despite the above, Schmaltz and Nezhat are combined, it is respectfully submitted that such combination would not result in the subject matter of claim 21. In particular, the Final Office Action relies upon the apparatus in Schmaltz as modified by the electrodes in Nezhat. Even if such an alleged combination were suggested by the prior art, the result is fundamentally different in the structure and function, as claimed.

Turning first to Schmaltz, the apparatus disclosed in Schmaltz has a substantially different structure. On each of the jaws 19 and 20, the respective electrode 11 and 12 comprises essentially the entire the clamping surface of each jaw. As shown in Figures 2, 3, 8 and 10, the electrode width is clearly not substantially narrower than the width of the clamping surface, as recited by claim 21.

Further, the Schmaltz patent clearly does not disclose or suggest an ablation device having ablation members that provide an ablation line through tissue which is substantially narrower than the width of the clamping surface, as also recited in claim 21. Schmaltz '996 discloses an instrument for sealing vessels such that a wide treatment zone is essential for sealing or fusing the opposed walls of such vessels together "without the use of sutures, staples or other material." (col. 3, lines 8-11; col. 5, lines 40-41) Such sealing surfaces 24 and 25 seal

together the vessel walls essentially along the entire width of the jaw which is substantially different from the claimed subject matter which forms a relatively narrow ablation line in cardiac tissue.

Turning to Nezhat, a bipolar surgical instrument is specifically described for "coagulating, cutting and necrosing tissue." (Column 1, lines 14-15). The Final Office Action particularly relies upon the embodiment in Figure 2E of Nezhat, which shows that each jaw 250 and 252 has two laterally spaced apart electrodes on each side of the jaw. However, in contrast to the reasoning relied upon in the Final Office Action, Nezhat consistently teaches away from the subject matter of claim 21.

In contrast to such claim, Nezhat clearly teaches that the embodiment of Figure 2E requires that the electrical current flows essentially between the entire width of the jaws. First electrodes 254, 258 are in opposed facing arrangement and are disclosed as having a first common polarity so electrical current will not flow between these two electrodes. Opposed facing second electrodes 256, 260 are laterally spaced on the jaw from the first electrodes 254, 258 and together share a second polarity which is opposite the polarity of the first electrodes 254, 258. The electrical current thus will flow from each first electrode 254, 258 to each second electrode 256, 260 such that the electrical current essentially flows along the entire width of the jaw to coagulate and cut tissue -- in contrast to the claimed conductive member/jaw arrangement for forming a relatively narrower ablation line only.

An alternative electrode/jaw arrangement is discussed in relation to Fig. 2E of Nezhat and such arrangement also operates to create an electrical current that essentially flows across the entire width of the jaw. In such alternative arrangement of Fig. 2E, the diagonal electrodes 254 and 260 have the same

polarity which is a different polarity than the other diagonal electrodes 256 and 258. The electrical current will flow between the pair of electrodes 254 and 256 on the first jaw 250 and between the pair of electrodes 258 and 260 on the second jaw 252, due to the opposite polarity of such electrodes, in addition to current flow between the jaws. Thus, in such arrangement, the electrical current still effectively spans the entire width of the jaw, in contrast to the claimed subject matter that forms a relatively narrow ablation line only.

Accordingly, if the electrodes of Nezhat were adapted into the structure of Schmaltz, the result would be a vein-sealing system that still effectively seals across the entire width of the jaw -- unlike the narrower ablation line of the claimed invention. Clearly, such a structure would not be suitable for forming narrow ablation lines in cardiac tissue without unduly harming other tissue. If used on cardiac tissue, the structure resulting from a combination of Schmaltz and Nezhat would clearly cause widespread destruction of tissue and sealing of opposed walls together.

Further, there are also other differences between claim 21 and the alleged combination of Schmaltz and Nezhat. Nezhat teaches a different jaw construction in Fig. 2E which does not provide three separate layers, as recited in new claim 21. The electrodes in Fig. 2E are shown having a cross-section associated with a metal material and the jaw construction is not described further. There is no discussion of three-layered construction which includes an elongated support member that supports substantially the entire electrode and which further includes an insulator disposed between such support member and the conductive member. If the electrodes of Nezhat are substituted for the removable electrodes 11 and 12 in the

apparatus of Schmaltz, the claimed structure does not result for this additional reason.

It Would Not Be Obvious To Modify The Alleged Prior Art to Reach The Claimed Subject Matter

First, it would not be obvious to modify Nezhat to meet the claimed subject matter because Nezhat expressly relies upon having electrodes of opposite polarity that are laterally spaced from one another and teaches away from the present claims:

> In contrast to prior art devices and methods, where electrodes of opposite polarity are generally engaged against directly opposed tissue surfaces, the present invention will position at least one positive electrode and at least one negative electrode on and/or into laterally spaced-apart sites on opposed tissue surfaces. (Emphasis added) (col.6, lines 6-11).

The laterally spaced electrodes of opposite polarity taught by Nezhat clearly results in a wider treatment coagulating zone that essentially cauterizes the entire lateral extent of tissue disposed between the jaws. Nezhat requires a wider treatment zone for the express purpose of "coagulating," "cutting" and "necrosing" tissue (col. 1, line 14, Col. 1, line 19 and Col. 2, line 2). Thus, any modification of Nezhat to meet claim 21 would be counterintuitive to these express purposes.

Further, it would not be obvious to modify Nezhat to meet the claim 21 because Nezhat specifically teaches away from devices having only two directly opposed electrodes of opposite polarity. In this regard, the express teachings in Nezhat actually discourage a narrow treatment zone and teach away from an instrument that forms a relatively narrower ablation line only, as in claim 21. Thus, there is an express teaching in Nezhat to not modify the electrodes in Nezhat to meet new claim 21.

A Combination Which Includes Another Prior Art Reference Also Would Not Make The Claimed Subject Matter Obvious

In addition, new claim 21 would not have been obvious based on the alleged combination of Schmaltz, Nezhat and/or Yamauchi 6,273,887. Further to the discussions above for the Schmaltz and Nezhat patents, it is further respectfully submitted that Yamauchi, either alone or in combination with these patents, would not render the claimed subject matter obvious because the subject matter of claim 21 is also fundamentally different from such combination.

First, such three-way combination is inconsistent with obviousness. Obviousness must be based on a teaching, suggestion or motivation in the alleged prior art combination to meet the claimed subject matter which, as described above, Schmaltz, Nezhat and Yamauchi do not provide. Moreover, it is respectfully submitted that if a three-way combination such as the above is necessary, such is itself evidence of non-obviousness.

Further, if Yamauchi is combined with Schmaltz and/or Nezhat, such combination does not render claim 21 unpatentable. In Figures 67, 74A and 74B, Yamauchi clearly characterizes the opposed electrode projections 510a, 510b, 549a and 549b as incision projections which are used to cut tissue, in contrast to claim 21.

Importantly, Yamauchi specifically describes the "incision projections" in Figure 67 as incising tissue where Yamauchi states that: "[w]hen jaws 508a and 508b are closed, the acute-angled portions 511 abut against each other to incise tissue. This embodiment is effective to incise a thin film or the like because the acute-angled portions 511 abut against each other." (column 38, lines 54-58) (emphasis added). As compared to Figure 67, Figure 74B does not show a fully closed position, but

it is apparent that the structures in Figures 67 and 74B are identical in this aspect. When the jaws in Figures 74A and 74B are fully closed, the acute-angled portions 550 of the incision projections 549a, 549b also will abut against each other to cut tissue.

Further, the incision projections 510a, 510b, 549a and 549b, as shown in Figures 67, 74A and 74B, are shown and described as having sharp V-shaped points or "acute-angled portions" 511 or 550 for cutting tissue. Indeed, Yamauchi shows in Figure 67 that the acute-angled portions 511 of the incision projections 510a, 510b touch each other so that tissue disposed between the jaws is cut when the jaws are closed.

Thus, any alleged combination which includes Yamauchi also clearly teaches cutting tissue clamped between the jaws in contrast to claim 21 which includes ablation member surfaces contoured to engage tissue without cutting tissue clamped between the jaws. Cutting of cardiac tissue is precisely what the present invention avoids.

There are also other differences between Yamauchi and the claimed subject matter. In Figures 67, 74A and 74B, Yamauchi fails to teach or suggest a narrow treatment zone between the jaws. In Figures 74A and 74B, current will flow from each uninsulated surface of one incision projection 549a and 549b to the other incision projection. There are four uninsulated surfaces on each incision projection 549a, 549b which include two parallel projecting surfaces (unnumbered) and two oblique surfaces 551 (Figure 74B). Thus, current flowing between the jaws in Figures 74A and 74B will flow through tissue which contacts each of these uninsulated surfaces resulting in a treatment zone which is not substantially narrower than the width of the clamping surface in contrast to the relatively narrower ablation line formed by the claimed subject matter.

Also, Yamauchi fails to teach or suggest a jaw arrangement that includes three separate elements or layers, as recited in claim 21. The jaws 548a and 548b in Figures 74A and 74B of Yamauchi are made of the incision projections 549a and 549b that are covered by insulation except for the exposed projecting portions 549a and 549b. Such jaws do not teach or suggest a support member in any respect and further do not teach an insulator that is disposed between the conductive member and the support member.

For these additional reasons, even an alleged combination that includes Yamauchi fails to teach or suggest the claimed subject matter.

Conclusion

For all of the above reasons, it is respectfully requested that new claims 21-31 would not be obvious. Reconsideration and allowance are respectfully requested.

Respectfully submitted,

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